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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

MERCK SHARP & DOHME B.V. and ORGANON USA INC., Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES LIMITED, Defendants.	Civil Action No. 20-18972 *Document Electronically Filed*

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Merck Sharp & Dohme B.V. ("Merck B.V.") and Organon USA Inc. ("Organon") (together, "Merck"), by their attorneys, bring this complaint against Defendants Teva Pharmaceuticals USA, Inc. ("Teva USA") and Teva Pharmaceutical Industries Limited ("Teva Ltd.") (together, "Teva Defendants"), and hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100, *et seq.*, including 35 U.S.C. § 271(e)(2), the Drug Price Competition and

Patent Term Restoration Act of 1984, 21 U.S.C. § 355(j) (the "Hatch-Waxman Act"), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, that arises out of Teva Defendants' submission of an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA") seeking approval to commercially manufacture, use, offer for sale, sell, and/or import the 500 mg/5 mL strength of a purported generic version of Bridion® (sugammadex) Injection prior to the expiration of U.S. Patent No. RE44,733 ("the '733 patent").

2. By a letter dated January 31, 2020, Teva USA notified Merck that Teva USA had submitted to the FDA ANDA No. 214126 for a purported generic version of sugammadex injection, 200 mg/2 mL ("Teva 200 mg/2 mL ANDA Products"), seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Teva 200 mg/2 mL ANDA Products in or into the United States, including New Jersey, prior to the expiration of the '733 patent ("Original ANDA Submission").

3. As a result, on March 12, 2020, Merck filed a related Complaint against Teva Defendants, *Merck Sharp & Dohme B.V. et al. v. Teva Pharmaceuticals USA Inc. et al.*, No. 20-2751-CCC-MF (D.N.J. Mar. 12, 2020), ECF No. 1, for patent infringement of the '733 patent (the "Related Action"). The Related Action was filed in connection with Teva Defendants' Original ANDA Submission to the FDA for the Teva 200 mg/2 mL ANDA Products.

PARTIES

4. Plaintiff Merck Sharp & Dohme B.V. ("Merck B.V.") is a corporation organized and existing under the laws of the Netherlands with its principal place of business at Waarderweg 39, Haarlem, Netherlands 2031 BN. Merck B.V. is an indirect, wholly owned subsidiary of Merck & Co., Inc., a New Jersey corporation, which has its principal place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033.

5. Plaintiff Organon USA Inc. ("Organon") is a corporation organized and existing under the laws of the State of New Jersey with its principal place of business at One Merck Drive, Whitehouse Station, New Jersey 08889. Organon is a wholly owned subsidiary of Merck & Co., Inc.

6. On information and belief, Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business, or currently completing the process of relocating its principal place of business to, Morris Coprorate Center III, 400 Interplace Parkway, Parsippany, New Jersey 07054. On information and belief, Teva USA is in the business of, among other things, manufacturing, promoting, marketing, selling, offering for sale, using, distributing, and importing into the United States, generic versions of branded pharmaceutical drugs for the U.S. market.

7. On information and belief, Teva USA has several places of business in the State of New Jersey, including but not limited to at the following business addresses: (1) 8 Gloria Lane, Fairfield, New Jersey 07004, and (2) 208 Passaic Avenue, Fairfield, New Jersey 07004.

8. On information and belief, Defendant Teva Pharmaceutical Industries Limited ("Teva Ltd.") is a corporation organized and existing under the laws of Israel, having a place of business at 5 Basel Street, Petah Tikva, 4951033, Israel. On information and belief, Teva Ltd. is in the business of, among other things, manufacturing, promoting, marketing, selling, offering for sale, using, distributing, and importing into the United States, generic versions of branded pharmaceutical drugs for the U.S. market, through various operating subsidiaries, including Teva USA.

9. On information and belief, Teva USA is a wholly owned subsidiary of Teva Ltd.

10. By a letter dated November 4, 2020 ("November Teva Notice Letter"), Teva USA notified Merck that Teva USA had submitted to the FDA an amendment to ANDA No. 214126 ("Teva's Amended ANDA") to add an additional strength of a purported generic version of sugammadex injection, 500 mg/5 mL ("Teva 500 mg/5 mL ANDA Products"), seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Teva 500 mg/5 mL ANDA Products in or into the United States, including New Jersey, prior to the expiration of the '733 patent.

11. On information and belief, Teva USA and Teva Ltd. acted in concert to prepare and submit Teva's Amended ANDA and the November Teva Notice Letter.

12. On information and belief, Teva USA and/or Teva Ltd. know and intend that upon approval of Teva's Amended ANDA, Teva USA and/or Teva Ltd. will manufacture, promote, market, sell, offer for sale, import, use, and/or distribute the Teva 500 mg/5 mL ANDA Products throughout the United States, including in New Jersey. On information and belief, Teva USA and Teva Ltd. are agents of each other and/or operate in concert as integrated parts of the same business group, including with respect to the Teva 500 mg/5 mL ANDA Products, and enter into agreements that are nearer than arm's length. On information and belief, Teva USA and Teva Ltd. participated, assisted, and cooperated in carrying out the acts complained of herein.

13. On information and belief, Teva Ltd. holds Drug Master File No. 33924 for sugammadex sodium.

14. On information and belief, following any FDA approval of Teva's Amended ANDA, Teva USA and Teva Ltd. will act in concert to manufacture, promote, market, sell, offer for sale, import, use, and/or distribute the Teva 500 mg/5 mL ANDA Products throughout the United States, including New Jersey.

JURISDICTION AND VENUE

15. Merck incorporates each of the preceding paragraphs 1–14 as if fully set forth herein.

16. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100, *et seq.*, including 35 U.S.C. § 271, for infringement of the asserted patent. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

17. This Court has personal jurisdiction over Teva USA because Teva USA is a corporation with a principal place of business in New Jersey or is currently in the process of relocating its principal place business to New Jersey and has at least one other regular and established place of business in New Jersey.

18. Teva USA is also subject to personal jurisdiction in New Jersey because, among other things, Teva USA has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being sued in this Court. On information and belief, Teva USA develops, manufactures, imports, markets, distributes, uses, offers to sell, and/or sells generic drugs throughout the United States, including in the State of New Jersey, and therefore transacts business within the State of New Jersey related to Merck's claims, and/or has engaged in systematic and continuous business contacts within the State of New Jersey.

19. Teva USA, in concert with Teva Ltd., has committed an act of infringement in this judicial district by filing ANDA No. 214126 with the intent to make, use, sell, offer for sale, and/or import the Teva 500 mg/5 mL ANDA Products in or into this judicial district, prior to the expiration of the '733 patent.

20. Teva Ltd. is subject to personal jurisdiction in New Jersey because, among other things, Teva Ltd. itself, and through its wholly owned subsidiary Teva Inc., purposely availed

itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being sued in this Court. On information and belief, Teva Ltd. itself, and through its wholly owned subsidiary Teva USA, develops, manufactures, imports, markets, distributes, uses, offers to sell, and/or sells generic drugs throughout the United States, including in the State of New Jersey, and therefore transacts business within the State of New Jersey related to Merck's claims, and/or has engaged in systematic and continuous business contacts within the State of New Jersey. In addition, Teva Ltd. is subject to personal jurisdiction in New Jersey because, on information and belief, it controls and dominates Teva USA, and therefore the activities of Teva USA in this jurisdiction are attributed to Teva Ltd.

21. Teva Defendants have taken the costly, significant step of applying to the FDA for approval to engage in future activities, including the marketing of the Teva 500 mg/5 mL ANDA Products, that will be purposefully directed at New Jersey and elsewhere in the United States.

22. On information and belief, Teva Defendants have systematic and continuous contacts with New Jersey; have established distribution channels for drug products in New Jersey; regularly and continuously conduct business in New Jersey, including by selling drug products in New Jersey, either directly or indirectly through their subsidiaries, agents, or affiliates; have purposefully availed themselves of the privilege of doing business in New Jersey; and derive substantial revenue from the sale of drug products in New Jersey.

23. Teva Ltd.'s 2020 third quarter report states that the United States is Teva Ltd.'s "largest market," and that in the third quarter of 2020, Teva Ltd. "led the U.S. generics market in total prescriptions and new prescriptions." *See* Teva Reports Third Quarter 2020 Financial Results at 5-6, *available at*

https://s24.q4cdn.com/720828402/files/doc_financials/2020/q3/Q3K-20_PR.combined_Final_Nov.4.2020.pdf (last visited November 16, 2020). Further, Teva Ltd.'s 2019 Securities and Exchange Commission 10-K form states that Teva Ltd. is "the leading generic drug company in the United States," and that Teva Ltd. "operate[s] worldwide with headquarters in Israel and a significant presence in the United States." *See* Teva Pharmaceutical Industries Limited 2019 Form 10-K at 3, *available at* http://d18rn0p25nwr6d.cloudfront.net/CIK-0000818686/5015938d-c8ed-48ab-bc5b-07ca0045cf2c.pdf (last visited November 16, 2020).

24. On information and belief, if Teva's Amended ANDA is approved, Teva Defendants will manufacture, market, promote, sell, offer for sale, import, use and/or distribute the Teva 500 mg/5 mL ANDA Products within the United States, including in New Jersey, consistent with Teva Defendants' practices for the marketing and distribution of other generic pharmaceutical products. On information and belief, Teva Defendants regularly do business in New Jersey, and their practices with other generic pharmaceutical products have involved placing those products into the stream of commerce for distribution throughout the United States, including in New Jersey. On information and belief, Teva Defendants' generic pharmaceutical products are used and/or consumed within and throughout the United States, including in New Jersey. On information and belief, the Teva's ANDA Products will be prescribed by physicians practicing in New Jersey, dispensed by pharmacies located within New Jersey, and used by patients in New Jersey. Each of these activities would have a substantial effect within New Jersey and would constitute infringement of the '733 patent in the event that the Teva 500 mg/5 mL ANDA Products are approved before the '733 patent expires.

25. On information and belief, Teva USA is registered as "Manufacturer and Wholesale" with the State of New Jersey's Department of Health under Registration No. 5003436.

26. On information and belief, Teva USA is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 0100250184.

27. On information and belief, Teva Defendants derive substantial revenue from generic pharmaceutical products that are used and/or consumed within New Jersey, and that are manufactured by Teva Defendants and/or for which Teva USA and/or Teva Ltd. is/are the named applicant(s) on approved ANDAs. On information and belief, various products for which Teva USA and/or Teva Ltd. is/are the named applicant(s) on approved ANDAs are available at retail pharmacies in New Jersey.

28. On information and belief, Teva USA has consented to jurisdiction in New Jersey in one or more prior cases arising out of the filing of its ANDAs, and/or has filed counterclaims in such cases. *Inspirion Delivery Scis., LLC v. Teva Pharm. USA, Inc. et al.*, No. 2:19-cv-10464-MCA-MAH (D.N.J. Apr. 19, 2019); *Celgene Corp. v. Teva Pharm. USA, Inc. et al.*, No. 2:19-cv-08758-ES-MAH (D.N.J. Mar. 19, 2019); *Adapt Pharma Operations Ltd. et al. v. Teva Pharm. USA, Inc. et al.*, No. 2:18-cv-09880-JLL-JAD (D.N.J. May 30, 2018).

29. On information and belief, Teva Ltd. has consented to jurisdiction in New Jersey in one or more prior cases arising out of the filing of its ANDAs, and/or has filed counterclaims in such cases. *See, e.g., Adapt Pharma Operations Ltd. et al. v. Teva Pharm. USA, Inc. et al.*, No. 2:18-cv-09880-JLL-JAD (D.N.J. May 30, 2018).

30. Additionally, this Court has personal jurisdiction over Teva Ltd. because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met as (a) Merck's claims arise

under federal law; (b) Teva Ltd. is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Teva Ltd. has sufficient contacts in the United States as a whole, including, but not limited to, by participating in the preparation and submission of Teva's ANDA, participating in the preparation and submission of DMF No. 33924 to the FDA, and/or manufacturing and/or selling pharmaceutical products distributed throughout the United States, including in this judicial district, such that this Court's exercise of jurisdiction over Teva Ltd. satisfies due process.

31. Venue is proper in this Court pursuant to 28 U.S.C. § 1400(b) as to Teva USA because, on information and belief, Teva USA has a regular and established place of business in New Jersey, and because, on information and belief, Teva USA has committed or aided, abetted, contributed to, and/or participated in the commission of, acts of infringement of the asserted patent that will lead to foreseeable harm and injury to Merck, which resides in this judicial district, by preparing or assisting in preparing Teva's Amended ANDA in New Jersey and/or with the intention of seeking to market the Teva 500 mg/5 mL ANDA Products nationwide, including within New Jersey.

32. Venue is proper in this Court as to Teva Ltd. because Teva Ltd. is a foreign entity who may be sued in any judicial district, including in the District of New Jersey. 28 U.S.C. § 1391(c)(3); *see also* 28 U.S.C. § 1400(b).

33. Teva did not contest personal jurisdiction or venue in New Jersey in the Related Action involving the Original ANDA submission. *See, e.g.*, *Merck Sharp & Dohme B.V. et al. v. Teva Pharmaceuticals USA Inc. et al.*, No. 20-2751-CCC-MF (D.N.J. Mar. 12, 2020), ECF No. 1 ¶ 31.

34. Teva USA has informed Merck that it will not contest personal jurisdiction or venue in the United States District Court for the District of New Jersey for purposes of this action.

THE PATENT-IN-SUIT

35. Merck B.V. is the owner and assignee of the ’733 patent, entitled “6-Mercapto-Cyclodextrin Derivatives: Reversal Agents For Drug-Induced Neuromuscular Block” (attached as Exhibit A). Merck B.V. has the right to enforce the ’733 patent.

36. The ’733 patent was duly and legally issued on January 28, 2014. The ’733 patent was a reissue of U.S. Patent No. 6,670,340, which was duly and legally issued on December 30, 2003.

37. The ’733 patent includes claims that recite 6-per-deoxy-6-per-(2-carboxyethyl)thio-γ-cyclodextrin, compositions containing 6-per-deoxy-6-per-(2-carboxyethyl)thio-γ-cyclodextrin, methods of using 6-per-deoxy-6-per-(2-carboxyethyl)thio-γ-cyclodextrin, and kits containing 6-per-deoxy-6-per-(2-carboxyethyl)thio-γ-cyclodextrin.

38. 6-Per-deoxy-6-per-(2-carboxyethyl)thio-γ-cyclodextrin is also referred to as sugammadex.

39. The FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations (“Orange Book”) lists the expiration of the ’733 patent as January 27, 2026. On June 24, 2020, the United States Patent and Trademark Office (“PTO”) issued a Certificate Extending Patent Term, wherein the PTO granted 5 years of patent term extension for the ’733 patent (attached as Exhibit B). Therefore the expiration of the ’733 patent is January 27, 2026.

THE BRIDION® DRUG PRODUCT

40. Organon is the holder of New Drug Application (“NDA”) No. 022225, under which the FDA approved the commercial marketing of Bridion® (sugammadex) Injection

("Bridion®") on December 15, 2015, under Section 505(a) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(a). Bridion® is approved for the reversal of neuromuscular blockade induced by rocuronium bromide and vecuronium bromide in adults undergoing surgery. Bridion® is distributed in the United States by Merck Sharp and Dohme Corp., a wholly owned subsidiary of Merck & Co., Inc., in 200 mg/2 mL and 500 mg/5 mL strengths in a single-dose vial for bolus injection. A true and correct copy of the current prescribing information for Bridion® is attached as Exhibit C.

41. Bridion® is a first-in-class drug that works differently than prior agents used for the reversal of neuromuscular blockade. The active ingredient in Bridion®, sugammadex, is a modified cyclodextrin that acts by directly encapsulating, binding, and inactivating agents used by healthcare providers to induce neuromuscular blockade in patients undergoing surgery, e.g., rocuronium or vecuronium, to reverse their effects. After intravenous injection, Bridion® distributes through plasma and binds to such neuromuscular blocking agents ("NMBAs") to form a complex. This process reduces the amount of NMBA available to bind to nicotinic cholinergic receptors in the neuromuscular junction, resulting in the reversal of neuromuscular blockade.

42. By this mechanism, Bridion® also avoids several of the side effects associated with prior reversal agents, such as acetylcholinesterase inhibitors. Traditional reversal agents are co-administered with other agents to manage these side effects, but the co-administered agents can cause a number of additional side effects. Moreover, Bridion® is capable of reversing the complete and prolonged block of neuromuscular function (known as "profound block") that can occur with the administration of NMBAs. Further, intravenous administration of sugammadex results in more rapid recovery from moderate or deep neuromuscular blockade in patients undergoing surgery who received rocuronium or vecuronium, as compared to neostigmine or

succinylcholine. Because of at least these unique features, Bridion® has been viewed as a significant advance in the field of anesthesiology.

43. Bridion®, as well as methods of using Bridion®, are covered by one or more claims of the '733 patent. The '733 patent has been listed in connection with NDA No. 022225 in the FDA's Orange Book.

DEFENDANTS' AMENDED ANDA AND NOTICE OF PARAGRAPH IV CERTIFICATION

44. On information and belief, Teva Defendants have submitted or caused the submission of Teva's Amended ANDA to the FDA under 21 U.S.C. § 355(j), to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of the Teva 500 mg/5 mL ANDA Products, as a purported generic version of Bridion®, prior to the expiration of the '733 patent.

45. On information and belief, the FDA has not yet approved Teva's Amended ANDA.

46. In the November Teva Notice Letter, Teva USA notified Merck of the submission of an amendement to Teva's ANDA to the FDA to include an additional strength of Sugammadex Sodium Injection, Eq. 500 mg base/5 mL. The purpose of this submission was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Teva 500 mg/5 mL ANDA Products prior to the expiration of the '733 patent.

47. In the November Teva Notice Letter, Teva USA acknowledged that the Reference Listed Drug for Teva's Amended ANDA is Bridion®. Bridion® is indicated for the reversal of neuromuscular blockade induced by rocuronium bromide and vecuronium bromide in adults undergoing surgery.

48. In the November Teva Notice Letter, Teva USA also notified Merck that, as part of its Amended ANDA, Teva USA had filed a purported Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '733 patent.

49. On information and belief, Teva USA submitted its Amended ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '733 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of the Teva 500 mg/5 mL ANDA Products.

50. In the November Teva Notice Letter, Teva USA stated that the Teva 500 mg/5 mL ANDA Products contain sugammadex as an active ingredient.

51. On information and belief, Teva Defendants, through their own actions and through the actions of their agents, affiliates, and subsidiaries, prepared and submitted Teva's Amended ANDA, and intend to further prosecute Teva's Amended ANDA. On information and belief, if the FDA approves Teva's Amended ANDA, Teva Defendants will manufacture, offer for sale, or sell the Teva 500 mg/5 mL ANDA Products within the United States, or will import the Teva 500 mg/5 mL ANDA Products into the United States. On information and belief, if the FDA approves Teva's Amended ANDA, Teva Defendants, through their own actions and through the actions of their agents, affiliates, and subsidiaries, will actively induce or contribute to the manufacture, use, offer for sale, sale, or importation of the Teva 500 mg/5 mL ANDA Products in or into the United States.

52. Merck brings this action within forty-five days of receipt of the November Teva Notice Letter. Accordingly, Merck is entitled to a stay of FDA approval pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

COUNT I – INFRINGEMENT OF THE '733 PATENT

53. Merck incorporates each of the preceding paragraphs 1–52 as if fully set forth herein.

54. The Teva 500 mg/5 mL ANDA Products, and the use of the Teva 500 mg/5 mL ANDA Products, are covered by one or more claims of the '733 patent, including at least claim 1 of the '733 patent, because claim 1 of the '733 patent encompasses the sugammadex utilized in the Teva 500 mg/5 mL ANDA Products.

55. In the November Teva Notice Letter, Teva USA did not specifically contest infringement of any claims of the '733 patent.

56. Teva Defendants' submission of Teva's Amended ANDA with a Paragraph IV Certification for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Teva 500 mg/5 mL ANDA Products in or into the United States before the expiration of the '733 patent is an act of infringement of the '733 patent under 35 U.S.C. § 271(e)(2)(A).

57. If approved by the FDA, Teva Defendants' commercial manufacture, use, importation, sale, and/or offer for sale of the Teva 500 mg/5 mL ANDA Products in or into the United States will directly infringe, contribute to the infringement of, and/or actively induce the infringement of one or more claims of the '733 patent under 35 U.S.C. § 271(a)-(c).

58. On information and belief, Teva Defendants will engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Teva 500 mg/5 mL ANDA Products in or into the United States immediately and imminently upon approval of Teva's Amended ANDA.

59. The commercial manufacture, use, sale, offer for sale, or importation of the Teva 500 mg/5 mL ANDA Products in or into the United States would infringe one or more claims of the '733 patent.

60. On information and belief, the commercial manufacture, use, sale, offer for sale, or importation of the Teva 500 mg/5 mL ANDA Products in accordance with, and as directed by, its proposed product labeling would infringe one or more claims of the '733 patent.

61. On information and belief, upon FDA approval of Teva's Amended ANDA, Teva Defendants will, through their own actions or through the actions of their agents, affiliates, and subsidiaries, market and/or distribute the Teva 500 mg/5 mL ANDA Products to resellers, pharmacies, hospitals, clinics, healthcare professionals, and other end users. On information and belief, Teva Defendants will knowingly and intentionally accompany the Teva 500 mg/5 mL ANDA Products with a product label or product insert that will include instructions for using or administering the Teva 500 mg/5 mL ANDA Products, which are substantially similar to the instructions in the prescribing information for Bridion®, attached as Exhibit C, and which, if followed, will infringe the '733 patent. Accordingly, Teva Defendants will induce resellers, pharmacies, hospitals, clinics, healthcare professionals, and other end users of the Teva 500 mg/5 mL ANDA Products to directly infringe the '733 patent. On information and belief, Teva Defendants will encourage acts of direct infringement with knowledge of the '733 patent and knowledge that Teva Defendants are encouraging infringement.

62. On information and belief, Teva Defendants plan and intend to, and will, actively induce infringement of the '733 patent when Teva's Amended ANDA is approved, and plan and intend to, and will, do so immediately and imminently upon approval. Teva Defendants' activities will be done with knowledge of the '733 patent and specific intent to infringe that patent.

63. On information and belief, Teva Defendants know that the Teva 500 mg/5 mL ANDA Products and proposed labeling are especially made or adapted for use in infringing the '733 patent, that the Teva 500 mg/5 mL ANDA Products are not a staple article or commodity of commerce, and that the Teva 500 mg/5 mL ANDA Products and accompanying proposed labeling are not suitable for substantial noninfringing use. On information and belief, Teva Defendants plan and intend to, and will, contribute to infringement of the '733 patent immediately and imminently upon approval of Teva's Amended ANDA.

64. Notwithstanding Teva Defendants' knowledge of the claims of the '733 patent, Teva Defendants have continued to assert their intent to manufacture, use, offer for sale, sell, distribute, and/or import the Teva 500 mg/5 mL ANDA Products with its product labeling in or into the United States following FDA approval of Teva's Amended ANDA prior to the expiration of the '733 patent.

65. The foregoing actions by Teva Defendants constitute and/or will constitute direct infringement of the '733 patent; active inducement of infringement by others of the '733 patent; and contribution to the infringement by others of the '733 patent.

66. On information and belief, Teva USA, in concert with its agents, subsidiaries, and affiliates including Teva Ltd., filed Teva's Amended ANDA with a Paragraph IV Certification without adequate justification for asserting that the '733 patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, sale, or importation in or into the United States of the Teva 500 mg/5 mL ANDA Products. On information and belief, Teva Defendants have acted with full knowledge of the '733 patent and without a reasonable basis for believing that they would not be liable for direct infringement of the '733 patent; active inducement of infringement by others of the '733 patent; and/or contribution to the

infringement by others of the '733 patent. On information and belief, the direct and indirect infringement by Teva Defendants of the '733 patent was and is willful. Teva Defendants' conduct renders this case "exceptional" under 35 U.S.C. § 285.

67. Merck will be substantially and irreparably damaged by infringement of the '733 patent. Unless Teva Defendants are enjoined from directly infringing the '733 patent, actively inducing infringement of the '733 patent, and contributing to the infringement of the '733 patent, Merck will suffer irreparable injury. Merck has no adequate remedy at law, and considering the balance of hardships between Merck and Teva Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of an injunction.

PRAYER FOR RELIEF

WHEREFORE, Merck requests the following relief:

(a) A judgment that the '733 patent has been infringed under 35 U.S.C. § 271(e)(2) by Teva Defendants' submission to the FDA of Teva's Amended ANDA;

(b) A judgment, pursuant to 35 U.S.C. § 271(e)(4)(A), ordering that the effective date of any FDA approval of the commercial manufacture, use, or sale of the Teva 500 mg/5 mL ANDA Products, or any other drug product that infringes or the use of which infringes the '733 patent, be not earlier than the expiration date of the '733 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A preliminary and permanent injunction, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., enjoining Teva Defendants, and all persons acting in concert with Teva Defendants, from the commercial manufacture, use, offer for sale, or sale in the United States, or importation into the United States of the Teva 500 mg/5 mL ANDA Products, or any other drug product covered by or whose use is covered by the '733 patent, prior to the expiration of the '733 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A judgment declaring that the commercial manufacture, use, offer for sale, or sale in the United States, or importation into the United States of the Teva 500 mg/5 mL ANDA Products, or any other drug product that is covered by or whose use is covered by the ’733 patent, prior to the expiration of the ’733 patent, inclusive of any extension(s) and additional period(s) of exclusivity, will infringe, induce the infringement of, and contribute to the infringement by others of the ’733 patent;

(e) A declaration that Teva Defendants’ commercial manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the Teva 500 mg/5 mL ANDA Products, or inducing or contributing to such conduct, would constitute infringement of one or more claims of the ’733 Patent by Teva Defendants under one or more of 35 U.S.C. § 271(a), (b), and (c);

(f) An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Teva Defendants engage in the commercial manufacture, use, offer for sale, or sale in the United States, or importation into the United States of the Teva 500 mg/5 mL ANDA Products, or any product that infringes the ’733 patent, or induces or contributes to such conduct, prior to the expiration of the ’733 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(g) A judgment that Teva Defendants willfully and deliberately infringed the ’733 patent;

(h) A declaration that this is an exceptional case and an award of attorney’s fees pursuant to 35 U.S.C. § 285;

(i) Costs and expenses in this action; and

(j) Such further and other relief as this Court may deem just and proper.

Dated: December 14, 2020
Newark, New Jersey

Respectfully submitted,

s/ William P. Deni, Jr.

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